



**IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE**

Appl. No. : 10/522,401

Applicant(s) : Taishi YOSHIDA et al.

Filed : January 19, 2005

For : PREVENTIVE AGENTS FOR
DIABETES MELLITUS

TC/A.U. : 1646

Examiner :

Docket No. : 04818CIP/HG

Confirm. No. : 6305

Customer No. : 01933

Express Mail Mailing Label
No.: EV 478 459 886 US
Date of Deposit: May 3, 2005

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Lorraine Dobies
Lorraine Dobies

In the event that this Paper is late filed, and the necessary petition for extension of time is not filed concurrently herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by check attached hereto, authorization to charge the extension fee, or any other fee required in connection with this Paper to Account No. 06-1378.

**SUPPLEMENT TO INFORMATION DISCLOSURE STATEMENT
FILED JANUARY 19, 2005 AND TRANSMITTAL OF ENGLISH
TRANSLATION OF PRELIMINARY EXAMINATION REPORT**

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

S I R :

The enclosed Forms PTO/SB/08A and PTO/SB/08B identify all of the references cited in the International Search Report of WO 2004/009118A1 which is the 18-month publication of Japanese Patent Application No. PCT/JP2003/009348 filed July 23, 2003, of which the present application is a Continuation-in-Part Application. Because priority is claimed under 35 USC 120, copies are not required. However, for the convenience of the Examiner copies are enclosed.

In addition, annexed hereto are copies of publications listed and in the above-identified application.

In the following list numbers 1 to 8 are identified in the International Search Report; also numbers 1 to 5 are cited in the specification as well. Numbers 9 and 10 are cited on page 2 of the specification; numbers 11-13 are cited on page 11 of the specification and number 14 is cited on page 16 of the specification:

1. WO 01/47935
2. J Med Chem. 2002 Aug 29;45(18):3865-77
3. Bioorg Med Chem Lett. 2001 Jan 8;11(1):17-21
4. WO 99/47549
5. N Engl J Med. 2002 Feb 7;346(6):393-403
6. Diabetes. 1980 Jan;29(1):41-9
7. N Engl J Med. 1994 Nov 3;331(18):1188-93
8. Diabetes Care. 1997 Feb;20(2):188-93
9. Diabetologia 1995;38:585-591
10. Diabetes Care 1999;22:920-924
11. Journal of Japan Diabetes Society 1999;42(5):385-404
12. Diabetes Care 1997;20:1183-1197
13. Diabetic Medicine 1998;15:539-553
14. Diabetes Research and Clinical Practice 1993;19: 49-58

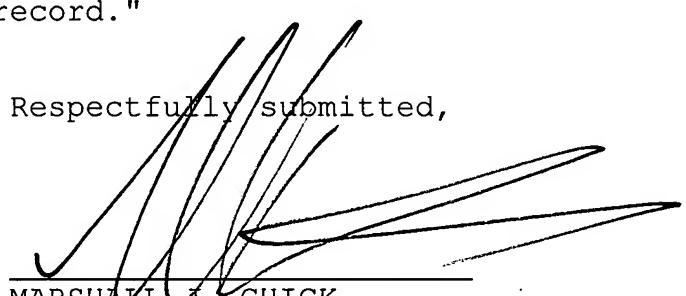
The relevance of these documents is their citation in the International Search Report and their discussion in the specification. A copy of the International Search Report is enclosed for the convenience of the Examiner.

Enclosed is an English translation of the PRELIMINARY EXAMINATION REPORT issued by WIPO (Form PCT/IPEA/409, 6 pages) and including a statement concerning several previously cited documents.

It is requested that the publications be considered with respect to the patentability of the present invention and that an initialed copy of the enclosed Forms PTO/SB/08A and PTO/SB/08B be returned to applicants to indicate that such publications have been considered and made "of record."

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PTO/SB/08A (08-00)

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/522,401		
		Filing Date	January 19, 2005		
		First Named Inventor	Taishi YOSHIDA		
		Group Art Unit	1646		
		Examiner Name			
Sheet	1	of	3	Attorney Docket Number	04818CIP/HG

U.S. PATENT DOCUMENTS

Exam. Units*	Cite No ¹	Document Number	Kind Code ²	Name of Patentee or Applicant	Publication Date MM-DD-YYYY	Relevant Portion

FOREIGN PATENT DOCUMENTS

Exam. Units*	Cite No ¹	Offc ³	Document Number ⁴	Kind Code ⁵	Name of Patentee or Applicant	Publication Date MM-DD-YYYY	Relevant Portion	T ⁶
		WIPO	WO 01/47935	A2	Metabasis Ther.	07-05-2001		
		WIPO	WO 99/47549	A1	Ontogen Corp.	09-23-1999		

Examiner Signature		Date Considered	
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* EXAMINER: Initial if document considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Place a check here if English translation is attached.

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Sheet	2	of	3	Attorney Docket Number	04818CIP/HG

OTHER PRIOR ART - NON-PATENT LITERATURE DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		<p>WRIGHT, et al., "Anilinoquinazoline Inhibitors of Fructose-1,6-Bisphosphatase Bind at a Novel Allosteric Site: Synthesis, In Vitro Characterization, and X-ray Crystallography", <u>J. Med. Chem.</u>, 29 August, 2002 (29.08.02); 45(18): 3865-77</p> <p>WRIGHT, et al., "Allosteric inhibition of fructose-1,6-bisphosphatase by anilinoquinazolines.", <u>Bioorg. Med. Chem. Lett.</u>, 08 January 2001 (08.01.01); 11(1):17-21</p> <p>KNOWLER, et al., "Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin.", <u>N. Engl. J. Med.</u>, 07 February 2002 (07.02.02); 346(6):393-403.</p> <p>SARTOR, et al., "Ten-year follow-up of subjects with impaired glucose tolerance: prevention of diabetes by tolbutamide and diet regulation.", <u>Diabetes</u>, 1980 January; 29(1):41-9.</p> <p>NOLAN, et al., "Improvement in glucose tolerance and insulin resistance in obese subjects treated with troglitazone.", <u>N. Engl. J. Med.</u>, 03 November 1994 (03.11.94); 331(18):1188-93.</p> <p>ANTONUCCI, et al., "Impaired glucose tolerance is normalized by treatment with the thiazolidinedione troglitazone.", <u>Diabetes Care</u>, 1997 February; 20(2):188-93.</p>	
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Examiner Initials ¹	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of article, title of item, date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		<p>English translation of International Preliminary Examination Report Form PCT/IPEA/409 in International Application No. PCT/JP2003/009348</p> <p>YAMASAKI et al., "Asymptomatic Hyperglycaemia is associated with increased intimal plus medial thickness of the carotid artery", <u>Diabetologia</u>, 1995; 38:585-591</p> <p>TOMINAGA et al., "Impaired Glucose Tolerance Is a Risk Factor for Cardiovascular Disease, but Not Impaired Fasting Glucose", <u>Diabetes Care</u>, 1999, 22:920-924</p> <p>Journal of Japan Diabetes Society 1999; 42(5):385-404 (English Abstract is attached on pages 402-404)</p> <p>"REPORT OF THE EXPERT COMMITTEE ON THE DIAGNOSIS AND CLASSIFICATION OF DIABETES MELLITUS", <u>Diabetes Care</u>, 1997; 20:1183-1197</p> <p>ALBERTI, et al., "Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications", <u>Diabetic Medicine</u>, 1998; 15:539-553</p> <p>HOTTA et al., "The inhibitory action of buformin, a biguanide on gluconeogenesis from alanine and its transport system in rat livers", <u>Diabetes Research and Clinical Practice</u>, 1993, 19:49-58</p>	
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